REMARKS

In view of the adverse Decision on applicants' Petition to the Commissioner regarding the issue of new matter, applicants have amended the definitions of "mask body" and "rigid insert" so that they reflect the original language. Since applicants have reverted to the original language, these changes raise no new issues. Accordingly, this amendment should be entered into the file so that the objection to the specification under 35 USC § 132(a) can be rendered moot.

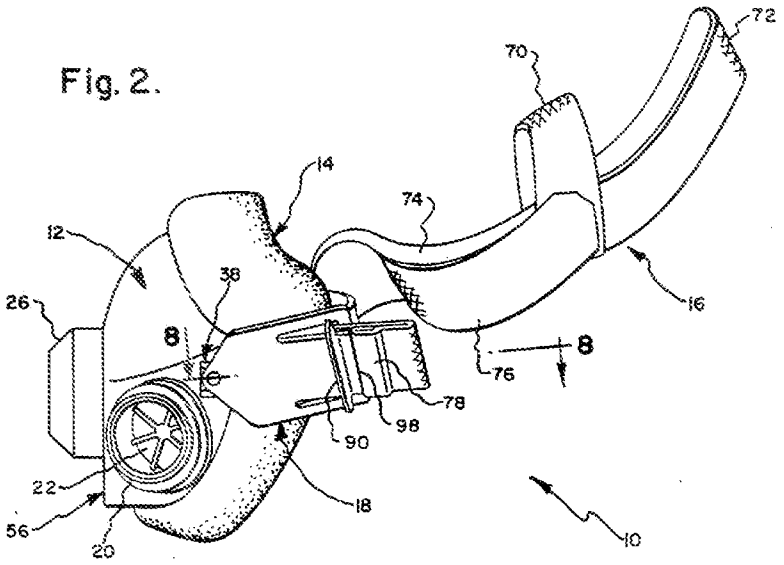
§ 102 Rejections

Claims 1, 3, 5, 8, 29 and 32 have been rejected under 35 USC § 102(b) as being anticipated by U.S. Patent 4,960,121 to Nelson et al. (Nelson). Applicants respectfully that this rejection cannot be sustained. Nelson does not teach or suggest a respirator that lacks a rigid insert.

Applicants' invention requires a mask body that lacks a rigid insert and that is non-elastomeric. Applicants' mask body also is constructed to deform such that the first and second cheek portions can move towards each other about an axis when the mask body is held stationary and a force is exerted on the nose and chin portions.

Nelson's respiratory mask 10 includes a hard shell 12 and a face seal 14:

Fig. 2.



The hard shell 12 is molded from a suitable material such as an ABS plastic (column 2, lines 36-37), and the face seal 14 is noted as being elastomeric (column 2, lines 26-37). Nelson's hard shell 12 meets applicants' definition of a rigid insert. Please note that the filter cartridges attach to Nelson's mask body at the hard shell. Nelson's mask body therefore includes both a rigid insert and an elastomeric member. Applicants have stated in their claim that the mask body lacks a rigid insert. As such, Nelson's inclusion of a rigid insert makes each of applicants' independent claims not anticipated. Further, there is no indication that Nelson's hard shell can be deformed such that the first and second cheek portions of the mask body can move towards each other about an axis when the mask is held stationary and a force is exerted on the nose and chin portions. More particularly, applicants' claim 19 specifies that the mask body of the invention is capable of exhibiting a deflection of at least 5 millimeters when an average force of 5 Newtons is applied to the mask body in accordance with the mask body deflection test, and claim 20 indicates that the deflection would be at least 10 millimeters when such a force is applied. Nelson does not indicate that its mask body is capable of exhibiting such deflections when 5 Newtons of force is applied. Nor is there any evidence that such would be inherent in Nelson's mask. For these reasons, applicants independent claims, and dependent claims 19 and 20, would not have been anticipated by Nelson.

Claims 4, 6, 7, and 18 have been rejected under 35 USC § 103(a) for claiming subject matter that would have been obvious over Nelson in view to U.S. Patent 6,062,221 to Brostrom et al. (Brostrom). Applicants respectfully submits that this rejection also cannot be sustained.

Respirator facepieces have been made from a soft compliant material, commonly rubber, that rests against the wearer's face and that forms a seal against the wearer's facial skin. The rubber typically is thick so that it can support filters and exhalation valves. See, for example, U.S. Patent 2,652,828 to Matheson and U.S. Patent 4,155,358 to McAlister et al. Thick rubber facepieces, however, can make the respirator heavy and uncomfortable to wear. Additionally, thick rubber adds to material and manufacturing costs. If the rubber is made thinner, however, the mask may have a tendency to collapse onto the user's face, particularly when tightening the harness while donning the respirator.

To make a facepiece lighter but not at the expense of reducing structural integrity, a thin rigid structural part has been incorporated into the facepiece. These rigid structural parts are

commonly produced through injection molding and are often referred to as "rigid inserts". The rigid insert provides adequate structure for supporting filter cartridges and valves. A soft compliant material, which conforms to a person's face, is disposed on or about the rigid insert to enable the mask to fit snugly over the wearer's nose and mouth. The use of a rigid insert in conjunction with a soft compliant portion tends to make the mask lighter and more comfortable to wear, particularly when compared to the previous masks that had used thick rubber throughout essentially the whole mask body to support the filter cartridges and valves. Masks that use a rigid insert in conjunction with a compliant face-contacting member are shown in U.S. Patent 6,016,804 to Gleason et al., U.S. Patent 5,592,937 to Freund, U.S. Patent 5,062,421 to Burns et al., and in U.S. Patent Application Serial No. 10/719,959 filed November 21, 2003, entitled "Respiratory Facepiece And Method Of Making A Facepiece Using Separate Molds."

Although masks that employ rigid inserts in conjunction with a soft compliant portion tend to be lighter and more comfortable to wear, they nonetheless can be somewhat more complicated to manufacture. Masks that use rigid inserts require multiple parts and the additional step of hermetically joining the insert to the soft, compliant, face-contacting portion.

The need for these additional parts and assembly steps can add to manufacturing costs. Applicants' invention provides a new respiratory mask that can overcome the need for thick facepieces, multiple parts, and multiple manufacturing steps to create the mask body. Unlike known respirators that used a thick rubber face piece to enable the cartridges to be adequately supported, the present invention may employ a thinner material that is sufficiently rigid and yet deformable at the cheeks so that the mask can adequately support filter cartridges and yet be sufficiently pliable to enable the mask to fit snugly and comfortably over a person's nose and at the cheek and chin portions. And unlike masks that used a rigid insert and a soft compliant portion, the present invention can make good contact to a wearer's face without using multiple facepiece parts and multiple manufacturing steps.

Applicants' invention provides a respiratory mask that comprises a mask body that lacks a rigid insert, that is non-elastomeric, and that is adapted for fitting over a person's nose and mouth. The mask body has a nose portion, a chin portion, first and second cheek portions, and an axis that extends from the nose portion to the chin portion. The mask body is constructed to deform such that the first and second cheek portions can move towards each other about the axis

when the mask body is held stationary and a force is exerted on the nose and chin portions. The respiratory mask also includes a harness that assists in supporting the mask on a wearer's face.

Applicants' invention also provides a method of making a respiratory mask, which method comprises: forming a mask body not weighing more than 35 g from a non-elastomeric plastic material that has a flexural modulus of greater than 500 MPa, the mask body being formed to a cup shape that has an average thickness less than 2 mm and that is adapted for fitting over a person's nose and mouth without inclusion of a rigid insert but with an integrally-formed nose portion, chin portion, central portion, and first and second cheek portions; and securing a harness to the mask body.

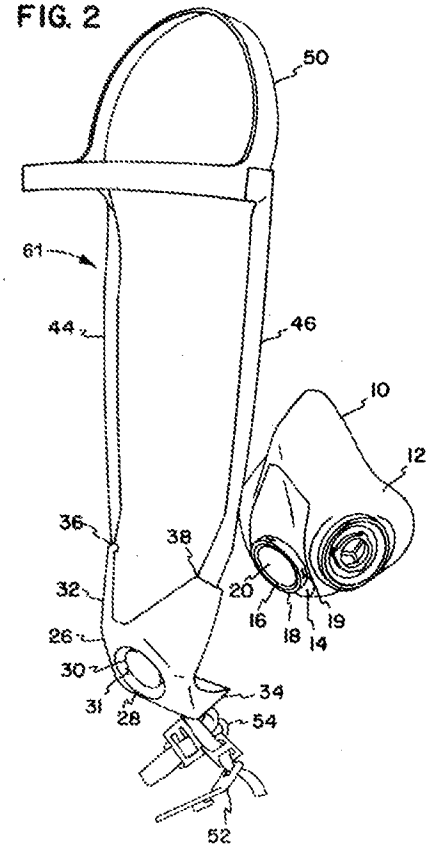
As indicated, previously known masks achieved a good fit over the nose and around the cheeks and chin by using either thick elastomeric rubber or a rigid insert in conjunction with an elastomeric type face seal. Applicants' invention, in contrast, does not possess a rigid structural insert to enable filter elements and valves to be adequately attached to the mask body but yet is able to provide a good fit at the cheek regions of a wearer's face, as well as over the nose and around the chin. The inventive mask body also exhibits substantial deflection about an axis that extends from the nose portion to the cheek portion of the mask. When tension is placed upon the straps that support the mask body on a wearer's face, and an opposing force is exerted at the nose and chin portions — as would occur when the mask is being worn — the cheek portions deflect inwardly towards each other. This form of deflection enables a good fit to be achieved on the wearer's face. This fit can be maintained during jaw movement of the wearer. For example, if a mask user is speaking while wearing the mask, adequate contact between the mask and the cheek portions can still be achieved. When using the inventive mask, an extension of the jaw draws the cheek portions toward each other so that a tight fit is still maintained.

Applicants' invention can overcome the need for thick facepieces, multiple parts, and multiple manufacturing steps to create the mask body. Unlike known respirators that used a thick rubber face piece to enable the cartridges to be adequately supported, applicants' invention may employ a thinner material that is sufficiently rigid and yet deformable at the cheeks so that the mask can adequately support filter cartridges and yet be sufficiently pliable to enable the mask to fit snugly and comfortably over a person's nose and at the cheek and chin portions. And unlike masks that used a rigid insert and a soft compliant portion, applicants' invention can make

good contact to a wearer's face without using multiple facepiece parts and multiple manufacturing steps.

As indicated above, Nelson does not describe a respirator that lacks a rigid insert in its face piece. Brostrom adds little or nothing to the features that are missing in Nelson. In fact, Brostrom also describes a respirator that has a rigid insert incorporated into its mask body:

FIG. 2



At column 3, lines 13-18, Brostrom indicates that the mask body 10 includes a seal portion 12 that "is configured to provide a seal against the face of the wearer" (this seal portion 12 is "constructed of a rubber-like material and is generally contoured to serve as a sealing surface) and further states that "[t]he central portion 14 is generally constructed of a rigid material and serves as a support for the seal portion 12." It is therefore apparent that Brostrom describes a respirator that also includes a rigid insert.

The Nelson/Brostrom combination does not suggest a respirator that meets the structural features of applicants' invention as recited in the independent claims; nor does it describe a respirator that exhibits the benefits provided by applicants' respirator.

In regard to the dependent claims, the noted deflection can be achieved when little force is applied to the mask — see claims 19, 20, and 34. Nelson and Brostrom both fail to provide any indication of such an ability. Further, these patents also fail to teach or suggest a mask body that has the flexural modulus of claims 14-17, 13, and 33. Nor do Nelson and Brostrom teach or suggest that the mask body can lack a rigid insert but also be light in weight as recited in claims 21-24 and 33.

In short, the structure and other features and advantages of the invention are not taught or suggested by the prior art. As such, applicants' invention is new and nonobvious, and the inventors should be awarded a patent for their new teachings.

Respectfully submitted,

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